[BUSINESS SOLUTION]

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Accelerating Product Development and Release with a Rapid, High-Precision Vitamin Analysis Method

Organization: Global Health Care Company
Technology: Waters ACQUITY UPLC System, Xevo TQ-S Mass Spectrometer, and MassLynx Mass Spectrometry Software

BACKGROUND

A global health care company recognized as a worldwide leader in nutrition science, research, and development, maintains over a dozen manufacturing sites around the world, including several sites in the United States. The company produces thousands of products under some of the world's most recognizable nutritional brands.

Given their expansive product portfolio, the company operates three central analytical laboratories to support numerous R&D and QA/QC activities. One US based central analytical laboratory, for which this study is focused, develops and performs analyses across a wide range of application areas including vitamins, carbohydrates, fatty acids, amino acids, minerals, and metals – approximately 220,000 analyses are processed annually. The technologies employed by the laboratory are equally diverse and include UPLC,® HPLC, GC, ion chromatography, mass spectrometry, and atomic absorption, among others.

CHALLENGE

The central analytical laboratory's support efforts are focused in two areas: the development of new or enhanced products and label confirmation of finished product. Results are used by R&D to better understand how new formulations impact efficacy, and stability, and if they meet the company's quality standards. For QC, the data determines if final product is within specification and therefore suitable for market release. For both groups, the speed at which data is generated and its precision is paramount.

A particular quantitative analysis of critical importance is that of seven water soluble vitamins – biotin, folic acid, niacin, pantothenic acid, pyridoxine, riboflavin, and thiamine. Company production requirements dictate a 2% to 3% intra-day method precision (measured as relative standard deviation or RSD) for this assay. Achieving the requisite precision threshold for three of the analytes has proven challenging with their legacy LC/MS/MS system – values generated were in the range of 5% to 7% RSD. As a consequence, a secondary and more cumbersome HPLC/UV method was necessary. To improve data precision, sample throughput, and help ensure product consistency, the laboratory sought an alternative LC/MS/MS platform.

SOLUTION

To meet requisite precision requirements for the LC/MS/MS vitamin analysis data, the laboratory implemented a solution comprised of the Waters® ACQUITY UPLC® System, Xevo® TQ-S Mass Spectrometer, and MassLynx® Mass Spectrometry Software.

The ACQUITY UPLC System combines advanced fluidics modules with sub-2-µm hybrid particle columns. This allows for higher efficiencies with a much wider range of linear velocities, flow rates, and backpressures compared to traditional HPLC. The Xevo TQ-S is a tandem quadrupole mass spectrometer that utilizes an off-axis ion source technology

known as StepWave.™ This technology allows for the detection of target compounds at very low concentrations, dilution of samples to reduce matrix effects, and the use of smaller sample volumes if desired. MassLynx Mass Spectrometry Software provides data acquisition, analysis, and management capabilities.

Their new UPLC/MS/MS platform is now routinely used for the quantitative analysis of all seven vitamins in a single 'dilute and shoot' assay with an approximate run time of 10 minutes. This method has replaced the legacy LC/MS/MS and HPLC/UV analyses.

BUSINESS BENEFITS

The central analytical laboratory has realized a number of operational benefits as a result of implementing the contemporary Waters UPLC/MS/MS system solution:

Data precision

- The RSD values for the LC/MS/MS water soluble vitamin assay have been reduced from 5% to 7% to the production requirement of 2% to 3 % for all analytes. According to one research scientist, the new system provides the 'precision equivalent to HPLC/UV with the sensitivity and selectivity of mass spectrometry'.

Product consistency

- The new method helps ensure that new products meet the same stringent quality standards as legacy products.

Laboratory productivity

- The legacy LC/MS/MS and secondary HPLC/UV methods have been replaced with a single injection method which has improved sample throughput without sacrificing precision.
- Quantifying the seven vitamins with the HPLC/UV approach had required five, 50 minute methods performed by five different analysts. The use of UPLC/MS/MS allows for the consolidation of five methods into a single 10-minute run. Total turnaround time for a sample was reduced from 2 to 3 days to 3 to 4 hours.
- MassLynx Software requires a minimal amount of training. According to the research scientist, 'Someone totally unfamiliar with the system can get set up and running and be as effective as someone who has used the system for six months to a year'.
- IntelliStart™ Software, which enables rapid, automated setup and checking of the system, has improved ease of use for analysts.

Sample characterization

- In the support of R&D efforts, the laboratory now has the ability to verify the identity of the vitamins using ion ratioing to ensure that the data reported is free from chromatographic or mass spectral interferences that previously went undetected.

'Green' operation

- UPLC separations have allowed for a 50% to 90% reduction in solvent usage compared to traditional HPLC.

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